REMARKS

Claims 26 – 33 and 50 – 55 are pending in this application.

In a Non-Final Office Action mailed June 9, 2008, claims 26 – 31 and 50 – 55 have been rejected under 35 USC 103(a) as being unpatentable over Brown (US Patent No. 5,307,263, hereinafter "Brown") in view of Levin et al. (US Patent No. 5,724,580, hereinafter "Levin et al."). This rejection is respectfully traversed.

The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). In the Examiner's rejection of these claims, the Examiner is providing "mere conclusory statements" without "rational underpinnings." It appears the Examiner is taking Official Notice, relying on "Common Knowledge" or "Well Known" prior art according to MPEP 2144.03, since various aspects of the claims are not taught by the prior art, including, but not limited to:

> "compiling a health report based on the test results and the additional diagnostic information, said health report including one or more of the following data items: a five-year risk of heart attack, a ten-year risk of heart attack, a cardiac age, an extended age, or a risk of stroke," and
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> a "health report including one or more of the following data items: a five-year risk of heart attack, a ten-year risk of heart attack, a cardiac age, an extended age, or a risk of stroke."

The Examiner has stated "it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Brown to extrapolate to a five year risk of heart attack." The Examiner states and takes Official Notice that "[s]imple algorithmic functions can extrapolate risk factors by taking in factors that contribute to cardiac events." Applicants challenge this taking of Official Notice, since providing patients with such forward looking predictions is not common in the medical arts; and these arts typically are oriented towards dealing with immediate issues as suggested by Levin et al., a reference cited by the Examiner. Applicants remind the Examiner that, according to

MPEP 2144.03, the Examiner must provide documentary evidence of this finding or, if the Examiner is relying on personal knowledge, the Examiner must provide a declaration or affidavit supporting this contention, so that Applicants have the opportunity to refute it.

The Examiner is further reminded that in *In re Eynde*, the court stated that "we reject the notion that judicial or administrative notice may be taken of the state of the art." 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1979). It appears that the Examiner is doing exactly this: taking Official Notice of the state of the art.

Furthermore, Applicants refer the Examiner to MPEP 2144.03 which states:

> Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

In respect to claims 26, 50, and 52, Applicants dispute that the providing of a five-year risk is "capable of such instant and unquestionable demonstration as to defy dispute." Therefore, the Official Notice taken by the Examiner is improper, and a prima facie case for obviousness has not been made in respect to this aspect of claims 26, 50, and 52. Ultimately, there is no disclosure or suggestion of this aspect of claims 26, 50, and 52.

Furthermore, the Examiner has failed to address claims 51 and 54. The art of record does not address the usage of a secure data system nor does the Examiner's Office Action. Therefore, **the finality of the next action is precluded**. Indeed, although the Summary of the Office Action indicates that claims 51 and 54 stand rejected, the Detailed Action omits any explanation of how any cited art anticipates [or renders obvious] these claims. Applicants respectfully submit that this omission amounts to a failure to articulate a prima facie case of unpatentablity, and the burden to rebut this "rejection" has not yet shifted to the Applicants. Consequently, a next Office Action rejecting claims

51 and 54 cannot properly be made final since only then would Applicants be obligated to rebut the rejection, presuming that such an Office Action sets forth a prima facie case. (See MPEP § 706.07(a))

Additionally, the Examiner has indicated that the "prior art does not fairly suggest or teach a test strip reader for reading a second type of test strip carrying a second sample of biological fluid and obtaining health related test results based on the second sample." Therefore, Applicants believe that claims 53 and 55 are patentable over the art of record and, therefore, stand wrongfully rejected.

Claims 32 and 33 have been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants thank the Examiner for this indication.

In view of the above remarks, Applicants believe the pending application is in condition for allowance. Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1848, under Order No. 023134.0128D1US from which the undersigned is authorized to draw.

Respectfully submitted,
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